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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,882	10/19/2004	Bodo Kuklinski	SONN:057US	6370

32425 7590 05/11/2006

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EXAMINER
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SCHUBERG, LAURA J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/511,882

Applicant(s)

KUKLINSKI ET AL.

Examiner

Laura Schuberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group I (claims 9-22) and species vitamin B1 in the reply filed on 04/24/2006 is acknowledged.

Claims 23-40 have been canceled by Applicant as being directed to non-elected inventions.

Claims 9-22 have been examined on the merits.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuchs et al (WO 01/97634 A1).

Claim 9 is drawn to a method of treating or preventing a skin disease in a subject comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix, and orally administering the composition to a subject.

Claim 10 is drawn to the method of claim 9, wherein the subject is a human.

Claim 11 is drawn to the method of claim 9, wherein the skin disease is further defined as a dry skin disease.

Claim 12 is drawn to the method of claim 9, wherein the skin disease is further defined as neurodermatitis.

Claim 13 is drawn to the method of claim 9, wherein the skin disease is further defined as psoriasis.

Claim 14 is drawn to the method of claim 9, wherein the matrix is a highly disperse silicon dioxide.

Claim 15 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a temperature of from 10 to 50OC.

Claim 16 is drawn to the method of claim 15, wherein the mare milk concentrate was dried at a temperature of from 35 to 40OC.

Claim 17 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a pressure of from 1 to 50 mbar.

Claim 18 is drawn to the method of claim 17, wherein the mare milk concentrate was dried at a pressure of from 10 to 30 mbar.

Claim 19 is drawn to the method of claim 9, further comprising drying the mare milk concentrate on the matrix.

Claim 20 is drawn to the method of claim 9, wherein the composition further comprises at least one essential fatty acid.

Claim 21 is drawn to the method of claim 20, wherein the essential fatty acid is a vegetable essential fatty acid.

Claim 22 is drawn to the method of claim 9, wherein the composition further comprises at least one of hydrogen carbonate, potassium, carbonate, citrate, calcium, magnesium, vitamin C, vitamin E, niacin, zinc, iron, beta-carotene, pantothenic acid, manganese, vitamin B6, vitamin B2, vitamin B1, copper, sodium, biotin, folic acid, molybdenum, selenium, xanthan, fructose, citric acid, or vitamin B 12. (Applicant has elected vitamin B1.)

Fuchs teaches an oral composition comprising highly unsaturated fatty acids on a biologically inert matrix (p.9) and drying the composition at a pressure of 10-30 mbar and a temperature of 30-36 ° C (p.12). The reference also teaches that it is advantageous to add mare's milk before drying and that dry concentrates of mare's milk have immunostimulatory effects on humans (p.15). It is also taught that it is especially

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advantageous if the composition is applied on a highly dispersed silicon dioxide matrix (p.12). The composition taught by the reference also contains linolenic acid (p.20) which is a vegetable essential fatty acid. Vitamin B1 is present in mare's milk and therefore inherently present in the composition. Fuchs teaches that highly unsaturated fatty acids are of a high biological and nutrition-medical relevance, especially for skin metabolism, neurodermatitis and psoriasis (p.3) and that the composition taught contains at least one unsaturated fatty acid. The disclosure of the skin disorders, neurodermatitis and psoriasis, and their connection with the need for the highly unsaturated fatty acids would indicate that administration of the referenced composition, which contains highly unsaturated fatty acids, would be necessary. According to Applicant's disclosure on page 9 of the specifications, dry skin diseases include neurodermatitis and psoriasis. In addition, the reference does teach where the subject is human and that the dry concentrates of mare's milk have beneficial immunostimulatory effects on humans (p.15). Therefore, each and every limitation of the claimed invention is taught and inherently anticipated by the disclosure of Fuchs.

However, in the alternative, if the referenced composition and its use are not the same as Applicant's and there is, in fact, no explicit disclosure for treating skin disorders, the reference composition would, nevertheless, have rendered to one of ordinary skill in the art at the time the invention was made the claimed method of treating skin disorders an obvious choice.

One of ordinary skill in the art would have been motivated to use the composition of Fuchs for the treatment and prevention of dry skin diseases such as neurodermatitis

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and psoriasis since the highly unsaturated fatty acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p.3). One of ordinary skill in the art would have had a reasonable expectation of success since Fuchs provides a composition that ensures a fine surface distribution of the oil particles so that sufficient quantities of unsaturated fatty acids are included (p.7).

Thus, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Equi Libre ([www.hestemelk.no/maresmilk.htm](http://www.hestemelk.no/maresmilk.htm)) describes that mare's milk contains vitamin B1.

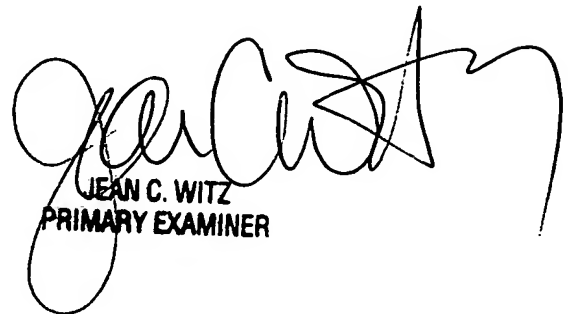
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura Schuberg



JEAN C. WITZ  
PRIMARY EXAMINER